IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EPIC PHARMA, LLC, Plaintiff, v. PFIZER INC., Defendant.	C.A. No.

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Epic Pharma, LLC ("Epic"), by and through counsel, hereby brings this Complaint for Declaratory Judgment against Defendant Pfizer Inc. ("Pfizer"), and alleges as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action under the Hatch-Waxman Act, the Declaratory Judgment Act and the Patent Laws of the United States. Epic seeks a judgment declaring that Epic has not infringed and will not infringe any valid and enforceable claim of United States Patent No. 6,268,489 ("the '489 patent") to enable Epic to bring its Azithromycin for Oral Suspension USP, which is the subject of the Abbreviated New Drug Application No. 207531 ("Epic's ANDA), to market at the earliest possible date under the applicable statutory and regulatory provisions and to allow the public to enjoy the benefits of generic competition for the product.

THE PARTIES

2. Plaintiff Epic is a privately held New York limited liability company having a place of business at 227-15 North Conduit Ave., Laurelton, New York 11413.

3. Upon information and belief, Defendant Pfizer is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

JURISDICTION AND VENUE

4. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355), and by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003), based upon an actual controversy between the parties to declare that Epic is free, upon approval by the Food and Drug Administration (the "FDA"), to manufacture, use, market, sell, offer to sell, or import its Azithromycin for Oral Suspension USP, 100 mg/5 mL and 200 mg/5 mL, as described in Epic's ANDA ("Epic's ANDA Product").

5. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Pfizer by virtue of its specific acts in, and its systematic and continuous contacts with, the State of Delaware, including conducting substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware, including but not limited to products containing azithromycin for oral suspension in dosage strengths of 100 mg/5 mL and 200 mg/5 mL. Personal jurisdiction over Pfizer in this Court is further appropriate because Pfizer is a Delaware corporation.

7. On information and belief, Pfizer regularly conducts or solicit business in Delaware, engages in other persistent courses of conduct in Delaware, or derives substantial revenue from services or things used or consumed in Delaware, including through their own actions or the actions of their affiliates and agents, demonstrating that Pfizer has continuous and systematic contacts with Delaware.

8. Furthermore, Pfizer has previously availed itself of this forum and affirmatively involved this Court's jurisdiction by litigating as plaintiff, including, for example, *Pfizer Inc. et al v. Macleods Pharmaceuticals, Ltd. et al.* No. 17-cv-00683 (D. Del.); *Pfizer Inc. et al v. Par Pharmaceutical, Inc.* No. 17-cv-00342 (D. Del.); and *Pfizer Inc. et al v. Breckenridge Pharmaceutical, Inc. et al.* No. 17-cv-00302 (D. Del.).

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

PATENT IN SUIT

10. On its face, the '489 patent, entitled "Azithromycin Dihydrate", indicates that it was issued by the United States Patent and Trademark Office on July 31, 2001. A copy of the '489 patent is attached hereto as Exhibit A.

11. According to the Electronic Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), the '489 patent expires on July 31, 2018.

12. According to the records at the United States Patent and Trademark Office, Pfizer Inc. is the assignee of the '489 patent.

STATUTORY BACKGROUND

13. The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 ("FDCA") provides that a company wishing to make a new drug must submit a New Drug Application ("NDA") to the FDA. In addition to the technical information, they also must include in the application the

patent number and the expiration date of any patent claiming the drug or claiming a method of using such drug that is the subject of the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(b)(1).

14. After the FDA approves an NDA, the FDA lists the patent information submitted by the brand name drug manufacturer in the Orange Book. *Id.*

15. In 1984, Congress passed the "Hatch-Waxman" amendments to the FDCA to expedite the process by which companies gain approvals to sell generic versions of approved new drugs by submitting an Abbreviated New Drug Application ("ANDA"). *See* The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of titles 21, 35 and 42 U.S.C.); 21 U.S.C. § 355(j)(2)(A).

16. The applicant of an ANDA needs to certify every patent listed in the Orange Book under the applicable NDA to the FDA "(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted". 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

17. With the submission of a "Paragraph IV" certification, the applicant of an ANDA must provide notice to the patent holder and the NDA holder, along with a statement of the factual and legal basis for the certification. The patent and NDA holder may commence a patent infringement action within 45 days of receiving the notice. *Id.* at § 355(j)(5)(C)(i)(I)(aa). If no action is brought within the 45-day period, the FDA may grant final approval to the ANDA.

18. In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") which includes a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement when the following conditions are met: (1) the 45-day period for the owner of the patent and NDA holder to bring suit has expired; (2) neither the owner of the patent nor the NDA holder brought an infringement action against the ANDA applicant before the expiration of such period; and (3) the applicant of the ANDA claiming non-infringement included in its Paragraph IV notice letter an offer of confidential access to the patent and NDA holders. *Id*. at § 355(j)(5)(C).

19. The MMA further provides that the first company to seek FDA approval of an ANDA containing a Paragraph IV certification (the "first filer") has the right to sell its drug without competition for 180 days (the "180-day exclusivity") beginning on the earlier of the date it begins commercial marketing of its generic drug product, or from the date of a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken. *Id*. at 355(j)(5)(B)(iv).

20. If the first filer does not begin commercial marketing, the FDA cannot grant final approval to any subsequently submitted ANDA for the same drug until the 180-day exclusivity has expired. *Id*.

21. However, the MMA also added provisions whereby the 180-day exclusivity may be forfeited in certain circumstances to prevent the exclusivity holder from blocking indefinitely the final approval of the subsequently-submitted ANDAs. *Id*. at § 355 (j)(5)(D).

22. In particular, the 180-day exclusivity is forfeited when the first filer fails to market the drug by the 75th day after the date a court enters a final decision from which no

appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed, or a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed, as a result of a declaratory judgment action brought by an ANDA applicant who has received tentative approval. *Id*. at 355(j)(5)(D)(i)(I).

23. If the 180-day exclusivity is forfeited, the FDA may approve any subsequently-submitted ANDA. *Id*. at 355(j)(5)(D)(iii).

FACTS

24 On information and belief, Pfizer is the holder of approved NDA No. 050710 for Zithromax® (azithromycin for oral suspension) 100 mg/5 mL and 200 mg/5 mL.

25. Pfizer identified the '489 patent to the FDA for listing in the Orange Book as a patent to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Id*. at § 355(b)(1).

26. As a consequence of listing the '489 patent in the Orange Book, Pfizer maintains, and has affirmatively represented to the FDA and the public, that the '489 patent claims the drug approved in NDA No. 050710, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant, including Epic, seeking FDA approval to market a generic version of the drug prior to the expiration of the '489 patent.

27. On or about June 12, 2014, Epic submitted its ANDA (No. 207531) to the FDA for proposed Azithromycin for Oral Suspension USP.

28. Epic also submitted a Paragraph IV certification in ANDA No. 207531, certifying that the '489 patent is invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, or sale of Epic's ANDA Product.

29. On February 10, 2015, Epic sent a letter to Pfizer notifying it that Epic filed ANDA No. 207531 with the FDA, including a Paragraph IV certification to the '489 patent (the "Notice Letter"). Pfizer received the Notice Letter on February 17, 2015. The Notice Letter included a detailed statement of the factual and legal bases for Epic's Paragraph IV certification and an Offer of Confidential Access to Epic's ANDA No. 207531 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

30. Epic's submission of ANDA No. 207531 to the FDA containing a Paragraph IV certification to the '489 patent creates the necessary case or controversy and subject matter jurisdiction for Epic to obtain declaratory judgment against Pfizer regarding infringement of the '489 patent.

31. As of April 6, 2015, the next business day occurring 45 days after Pfizer received the Notice Letter, Pfizer had not brought an action for infringement of the '489 patent against Epic. As of the date of this Complaint, Pfizer still has not brought an action for infringement of the '489 patent against Epic.

32. On information and belief, Lupin Pharmaceuticals, Inc. ("Lupin") was the first entity to file an ANDA referencing Pfizer's NDA 050710 with a Paragraph IV certification to the '489 patent and is eligible to receive the 180-day exclusivity period.

33. On information and belief, Lupin received final approval of its ANDA No. 065488 on May 15, 2015. However, as of the date of the filing of this Complaint, Lupin has not started commercial marketing of its product, which is the subject of its ANDA No. 065488.

34. Since Lupin has not launched its ANDA product, Epic cannot obtain final FDA approval and cannot market its ANDA product. The FDA will not approve Epic's ANDA until Lupin's 180-day exclusivity period is either forfeited or runs out.

35. On information and belief, no court has entered the "final decision" identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) with respect to the '489 patent. On information and belief, no court has entered a final decision from which an appeal has been or can be taken that the '489 patent is invalid or not infringed.

36. Epic received tentative approval of its ANDA No. 207531 on May 26, 2017 and has met the conditions necessary for the filing of a declaratory judgment: (1) the 45-day period for Pfizer to bring suit has expired; (2) Pfizer did not bring an infringement action against Epic before the expiration of such period; and (3) Epic's Notice Letter claiming non-infringement included an offer of confidential access to Pfizer.

37. Unless Epic obtains a court order finding the '489 patent not infringed, invalid, or unenforceable, Epic will be harmed by the inability to market its generic product. A declaratory judgment from this Court as to the non-infringement of the '489 patent will alleviate Epic's harm by allowing Epic to obtain final approval of Epic's ANDA Product and compete in the market for azithromycin suspension product.

38. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Epic and Pfizer regarding the infringement of the '489 patent over which this Court can and should exercise jurisdiction and declare the rights of the parties.

39. Epic is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Epic's ANDA Product does not and will not infringe any valid and enforceable claim of the '489 patent.

40. Absent the exercise of jurisdiction by this Court and such declaratory relief, Epic will be harmed by the substantial delay in its market entry for generic Zithromax®. Epic's injury can be redressed by the requested relief.

COUNT 1: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '489 PATENT

41. Epic repeats and realleges the preceding paragraphs as if fully set forth herein.

42. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of Epic's ANDA Product will infringe the '489 patent.

43. The '489 patent issued with two independent claims and one dependent claim.

44. Epic's ANDA Product does not meet each and every limitation of independent claims 1 and 2 at least because Epic's ANDA Product does not contain crystalline azithromycin dihydrate as required by claims 1 and 2 of the '489 patent.

45. Since Epic's ANDA Product does not meet each and every limitation of independent claim 2, Epic's ANDA Product does not meet each and every limitation of dependent claim 3.

46. Since Epic's ANDA Product does not meet each and every limitation of any claim of the '489 patent, the submission of Epic's ANDA does not constitute infringement of any claim of the '489 patent.

47. Epic is entitled to a judicial declaration that it has not infringed and does not infringe directly, by inducement, or by contribution of any valid or enforceable claim of the '489 patent.

48. Epic is entitled to a declaration that the commercial manufacture, use, sale, offer for sale or importation of Epic's ANDA Product does not and will not infringe directly, by inducement, or by contribution of any valid or enforceable claim of the '489 patent.

PRAYER FOR RELIEF

WHEREFORE, Epic respectfully requests the Court enter judgment in its favor and against Defendant as follows:

A. Declaring that the claims of the '489 patent have not been infringed by the filing of Epic's ANDA;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and importation of Epic's ANDA Product has not, , and will not infringe or induce or contribute to the infringement by others of, any valid or enforceable claim of the '489 patent;

C. Declaring that the FDA may approve Epic's ANDA without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the '489 patent is not infringed pursuant to 21 U.S.C. § 355G)(5)(B)(iii)(I)(aa); and that any other marketing exclusivity periods to which Plaintiff might otherwise be entitled (including any pediatric exclusivity) with respect to the '489 patent are shortened to expire upon the date of entry of judgment in this case;

D. Finding this case to be exceptional and awarding Epic its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

E. Awarding Epic its costs, expenses and reasonable attorneys' fees; and

F. Awarding Epic such other and further relief that this Court deems just and equitable under the circumstances.

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